

135 A1 > CLAIMS:

1. A method of preparing products containing moisture-sensitive materials, including biological materials such as proteins, peptides or live cells, comprising at least the steps:
 - 5 (i) providing a coating liquid comprising at least one active, a sugar polymer and a water soluble/miscible solvent;
 - (ii) providing a quantity of microparticles comprising at least water soluble gel forming solid particles;
 - (iii) fluidizing said quantity of microparticles within a processing chamber of a suitable apparatus to form a fluidized bed of said microparticles;
 - 10 (iv) spraying said coating liquid onto said fluidized bed from beneath the fluidized bed to coat said microparticles therewith under saturated moisture conditions; and
 - (v) allowing coated microparticles to dry.
2. A method according to claim 1 wherein one or more additional coating steps further coat the microparticles with an enteric coating, a film coating, a moisture repellent coating, and/or a taste-masking coating.
- 20 3. A method according to claim 1 or 2 wherein the microparticles are heat dried.
4. A method according to any one of claims 1 to 3 wherein the active comprises one or more proteins, peptides, or cells.
- 25 5. A method according to any one of claims 1 to 4 wherein the water soluble/miscible solvent is glycerol, propylene glycol, or a combination of glycerol and propylene.
- 30 6. A method according to any one of claims 1 to 5 wherein the sugar polymer is selected from a group comprising dextran, fructose, fruitose, glucose, invert sugar, lactitol, lactose, maltitol, maltodextrin,

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maltose, mannitol, sorbitol, sucrose, trehalose, isomalt, xylitol, polydextrose, or combination thereof.

7. A method according to any one of claims 1 to 6 wherein the water soluble gel forming solid particles comprising one or more water soluble gel forming solid particles selected from a group comprising acrylate and derivatives, albumin, alginates, carbomers, carrageenan, cellulose and derivatives, dextran, dextrin, gelatine, polyvinylpyrrolidone, and starch.

5 8. A method according to any one of claims 1 to 7 wherein the method is conducted in a moisture saturated environment.

10 9. A method according to any one of claims 1 to 8 wherein the method is conducted in an oxygen free environment.

15 10. A method according to any one of claims 1 to 9 wherein the coated microparticles are formed into a composition for injection, as a sublingual tablet, as an oral tablet, as a sustained release sublingual tablet, into microcapsules, pessaries, preconstituted solid dose for nasal spray or drops, aqueous drops, eye wash or drops, skin washing solutions, or as a feed premix.

20 11. A method according to any one of claims 1 to 9 wherein the said is a method for stabilizing biological materials.

25 12. A method according to any one of claims 1 to 11 wherein the microparticles are 50 microns to one millimetre particle size.

30 13. A method according to any one of claims 1 to 12 wherein the active is a hormone, cytokine or growth factor.

14. A method according to claim 13 wherein the active is selected from human or animal growth hormones, or derivatives thereof,

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erythropoietin, calcitonin, interferon, interleukin, insulin, or a colony stimulating factor.

15. A method according to any one of claims 1 to 12 wherein the active is
5 an enzyme.

16. A method according to claim 15 wherein the enzyme comprises
10 streptokinase, muramidase, pancreas, amylase, protease, lypase, cellulase, bromelain, or papain.

17. A method according to any one of claims 1 to 12 wherein the active is
15 glucan.

18. A method according to claim 17 wherein glucan is β -1,3-glucan.

19. A method according to any one of claims 1 to 12 wherein the active is
15 a microorganism.

20. A method according to claim 19 wherein the microorganism is one or
20 more of *Bifidus*, or *Lactobacilli*.

21. A product when produced by a method according to any one of claims
1 to 20.

25. 22. A composition comprising a core of microparticles coated with an
active and sugar polymer coating layer.

23. A composition according to claim 22 which is coated with an enteric
30 coating, a film coating, a moisture repellent coating, a taste-masking
coating, or one or more such coatings.

24. A composition according to claim 22 or 23 wherein the active
comprises a protein, peptide, or cell.

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25. A composition according to claim 24 wherein the active is a hormone, cytokine, or growth hormone, or a combination of any two or more thereof.

5 26. A composition according to claim 25 wherein the active is selected from a group comprising human or animal growth hormones, or derivatives thereof, erythropoietin, calcitonin, and interferon, and interleukin, insulin, and a colony stimulating factor.

10 27. A composition as claimed in claim 24 wherein the active is a microorganism.

28. A composition as claimed in claim 27 wherein the microorganism is one or more of *Bifidus*, or *Lactobacilli*.

15 29. A composition as claimed in any one of claims 22 to 24 wherein the active is an antidiarrhoea agent.

30. A composition as claimed in any one of claims 22 to 24 wherein the active is a growth promotant.

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31. A composition as claimed in any one of claims 22 to 30 which comprises microparticles of acrylate, or derivatives, albumin, alginates, carbomers, carrageenan, cellulose, or derivatives, dextran, dextrin, gelatin, polyvinylpyrrolidone, or starch.

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32. A composition as claimed in any one of claims 22 to 31 wherein said composition is in the form of an injection, as a sublingual tablet, as an oral tablet, as a sustained release sublingual tablet, microcapsules, pessaries, preconstituted solid dose for nasal spray or drops, aqueous drops, eye wash or drops, skin washing solutions, or as a feed premix.

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